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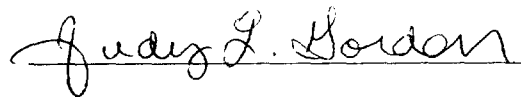
#### SECTION 14: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Submitter's name, address, telephone number, contact person, and date summary prepared;

- a. Chiron Vision Corporation  
555 West Arrow highway  
Claremont, CA 91711

- b. Contact Person: Judy F. Gordon, D. V. M.  
Vice President, Scientific Affairs



- c. Date Summary Prepared: January 26, 1996

2. Name of device, including trade name and classification name:

- a. Trade/Proprietary Name: Synergist™ Power Pack

- b. Classification Name: Phacofragmentation System

3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company: Chiron Intraoptics

Device: Phacotron™ Gold Multifunction Ultrasonic (Tmesis™) Handpiece

510(k): K925631

Date Cleared: July 29, 1993

- ) 4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):

The Synergist™ Power Pack is an accessory device that operates in conjunction with currently marketed Phaco Emulsifier Aspirator Systems used in ophthalmic surgery. The Synergist™ replaces the ultrasonic handpiece of the host console. As such, it is intended for use in cataract surgery or other ophthalmic surgical procedures where precision surgical tissue removal is required. The Synergist™ delivers two distinct surgical capabilities: 1) load compensating ultrasonic handpiece power, and 2) Tmesis™ multi-function handpiece capability.

The Synergist™ Power Pack consists of:

- Power Pack Console
- Connector Cables
- Tmesis™ multi-function handpiece,
- Adjunct Footswitch
- Ultra Tip™ Pack in various configurations

) The Synergist™ Power Pack utilizes the programmable features of the Phaco Emulsifier host console but contains no software or firmware. It is controlled by the amplified signal of the host console by measuring the handpiece output of the host console and establishing that exact power level to the connected handpiece. Displayed power levels and energy summations on the host console are precisely maintained by the Synergist™. The Power Pack neither provides or utilizes power from the host console.

5. Statement of intended use:

The Synergist™ Power Pack is intended for use in cataract surgery or other ophthalmic surgical procedures where precision surgical tissue removal is required.

6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.

<u>Characteristic</u>	<u>Synergist™ Power Pack</u>	<u>Phacotron™ Gold Multifunction Handpiece</u>
Intended use	Cataract/ophthalmic surgery	Cataract/ophthalmic surgery
Operating principle	Equivalent to US handpiece impedance matched	Equivalent to US handpiece impedance matched
	Console controlled via standard footswitch	Console controlled via standard footswitch
	External module	Internal module
	Independent power supply	Phaco console power supply
	Operating frequency-40khz	Operating frequency-40kHz

The operating principals listed above compare the principles of operation of the system with the module contained within the host console (predicate 510(k) ) and with the module contained in a external housing (subject 510(k)). The characteristics of the multifunction handpiece vs. predicate devices is set forth in the 510(k) for the Phacotron™ Gold Multifunction Handpiece, a copy of which is provided in Section 11.

Materials	Standard materials used in Phaco Emulsifier Aspirator consoles and handpieces	Standard materials used in Phaco Emulsifier Aspirator consoles and handpieces
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